Getting from Procedures and Approach to Innovation in Grantsmanship

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ABSTRACT

Call it innovation, creativity, imagination, cutting edge, paradigm shift, or any other term for new information, an assessment of innovation may now impact the final decision on awarding grants to investigators. What exactly is innovation and how does the reviewer perceive innovation in the research approach? Procedures, the approach, and innovation all have nuances in the grant application. This paper includes examples of all three grant application components in laymen's and scientific terms to demonstrate and investigate further their use in the grant application.

INTRODUCTION

The potential paths leading from technical procedures through the Scientific Approach to Innovation in a project can spell success for a grant application or be a complete disaster. New investigators sometimes have difficulty choosing the correct paths, particularly if they are in a hurry to get that first grant application out the door for reviewers' comments.

Unfortunately, too many new investigators choose to "short-circuit" the grant application process by not demonstrating a

thorough documentation and understanding of the procedures to be used, not relating how those incomplete procedures affect the scientific integrity of the proposal, and not understanding how the incomplete scientific approach affects the declaration of innovation within the proposed project. Instead, the view is often—"Well, it's not going to get funded anyway, so I'll just send it in and see what the reviewers tell me should be done". Reviewers are weary of directing the

scientific research agenda of other investigators through a comments section.

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Hence, there is a movement to eliminate grant applications that do not follow protocol or instructions of the agency prior to review AND to eliminate (with few comments) those applications for which little or no interest can be garnered. Usually, the scientific approach to the project is significantly flawed. Why are procedures, approach, and innovation important in the application? Consider the instructions and review criteria for a number of federal agencies. To provide some insight into the problems and some suggestions on how to correct these problems, definitions and dialogue on each of these components follow.

PROCEDURES

 \mathbf{P} rocedures include the conduct of an action or process in a mode that collects information. These are the processes that one follows religiously to bake the cake that always gets kudos at the community center buffet or that the investigator uses to get consistent results from a scientific experiment. Without procedures to follow, the operator of your community's water system might deliver clear, colorless water on one day, water that tastes good on another, and water that is safe to drink on the third day. What one wants that operator to do is to deliver water that is consistently colorless, clear, tasteless, and odorless, and is safe to drink all at one time, every day without fail—that is, consistent results. The pathway to the correct procedure for the water utility is an amalgamation of mathematical calculations, experience, trial and error, and structured experimentation to determine the best way to get the desired results. In that water varies by source (ground or surface) and the number and amounts of suspended solids, dissolved solids, and electrolytic qualities vary, this can be a daunting task. Yet, the water system is not approved until all procedures remove the impurities that affect safety and most other aspects of palatable drinkability. Over time, procedures may have to be or can be modified to fit a particular situation—too much rain with muddy

surface water, drought, high mineral levels in wells going dry, etc. On the same note, the electric utility company is charged with delivering current to your home that is safe, reliable, and at the appropriate power level so that it does not damage your appliances, clocks, and technology instrumentation. Changing a cake recipe to add a new twist or zing is fine for the community buffet attendees. Changing the procedure during the standardized data collection process because the data are not providing the expected results can be disastrous and expensive. Reviewers are very astute at discerning procedural flaws that will yield incomplete results or no new results, and/or make the stated scientific approach invalid. Good science requires good data sets.

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Some procedural errors occur because there is an assumption that Dr. X's procedure for purifying enzyme "A", for example, transfers to isolating enzyme "A" in a different organism. In that there are similarities, there will be differences. An inadequate testing of the procedure with the new organism may lead to difficulties in resolution of the data. Procedural

methodologies are always being transferred across organisms of different types. Consider the advent of gel electrophoresis to determine variability among organisms of different populations of the same species. The original gel and enzyme-resolution "recipes" and technical procedures were highly coveted and investigators went so far as to purchase reprints of dissertations that contained gel resolution recipes and to gather as many recipes from other groups as possible. The recipes for animal testing are more prolific and easier to transfer among species. The recipes for plants are highly species-specific. Successful resolution of enzyme banding was iffy even when working with individuals from related species as plants release chemical garbage contained within the trash bags of the leaves. When one prepares the plant extract for electrophoresis, the entire leaf is ground up, releasing the chemical garbage from its internal containers. This leads to faster degradation of the leaf enzymes, so special precautions must be taken to prevent degradation. To accommodate the variables, recipes for the gels used for electrophoresis of plants have to be modified, the enzyme-resolution recipes have to be more concentrated, and the procedure for electrical current passing through the gels may have to be modified. To obtain the resolution and consistency required for comprehensive data collection, it took one investigator more than a year to

develop a protocol for a specific species of plant before one piece of data was collected. Good science takes time and effort.

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The best advice for making sure that your procedures and experimental design are sound is to collect "pretend" data. Once the "pretend" data are recorded on an appropriate table, can one analyze the data using standard and/or ANOVA statistical tests? Once the analysis is done, have you gathered/compiled new information? If the answer is, "No", then it is back to the design board to modify the techniques. If one has not acquired enough data to answer this question, then the weakness may lie in the types of data to be collected and/or the number of trials to achieve significant results. If the investigator is to compare the results of several sets of pretend data that represent several different approaches AND the results do not make sense or have gaping holes in the analyses, then the procedures and tests of those procedures are flawed. Good science is accurate.

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The same consistency applies to other disciplines, such as education. One would not expect to introduce a new instructional technique designed for third-grade

mathematics after testing the new technique on children in grades 4-6. In political science, one change in party leadership during one election does not constitute a trend change. A one-day jump in the stock market indices does not indicate a bull market. Good science is applicable across many fields.

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SCIENTIFIC APPROACH

The approach is the method used or steps taken in setting about a task or a problem. First, the approach should be identified as the problem to be solved, as the critical need to be addressed, or as the gap in information to be filled. If it is a true open-ended scientific investigation, a hypothesis(es) should be stated. The statement of the specific aims or objectives to be accomplished is designed to prove or disprove the hypotheses. The broad base of the aim or objective further delineates the tests that are to be done to validate the hypothesis. Usually the hypothesis is directional in that it provides an educated guess as to the expected results. The educated guess is derived from the preliminary studies or data that were collected prior to writing the grant application. Second, the tests to be done to support the aims should have correct and

accurate procedures. There should be no "Aha, and then the miracle occurs!" gaps in the procedures left to the reviewer's imagination. All reviewers work differently in reviewing an application although some aspects of evaluation are similar. One such example is the reading of the hypothesis and one specific aim/objective. Each aim or objective is then followed individually through the significance description for the project and the approach with special attention paid to the procedural overview, selection criteria for inclusion and collection of data points generated during the procedures, how that information will be combined with information from the other aims/objectives, the statistical tests to determine significance and what new information will come from this combined effort. Good science is objective.

Although the testing for scientific investigation is quite rigorous, that rigidity transfers to other disciplines with peer-review systems. For educational-oriented grant applications, the objective must be fleshed out with not only the anticipated results, but also the evaluation criteria, an assignment of who is doing the work, the evaluation assessment type, and to whom the intervention is to be applied. Those applications in the humanities for performance-based project—concerts, plays, etc.—are subject to strict budgetary evaluations based on realistic anticipated revenues from endowments, membership

fees, gate sales, and sponsors. Until the reviewer can track every required aspect of the grant application to the discipline expectations, gaps in information will cause applications to be unfunded.

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While the approach is formulated to address the stated hypothesis and aims, just addressing these is not sufficient. There must be an end point at which data collected are analyzed and interpreted. One cannot just work as hard and fast as possible to gather as much information as possible during the grant award for inclusion in a final report. Analysis is paramount to good science.

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INNOVATION

To innovate is to introduce new things or methods that are entirely new or that make changes in something already established. Call it innovation, creativity, imagination, cutting edge, paradigm shift, or any other term for new information or new use of information, an assessment of innovation may now impact the final decision on awarding grants to investigators. In that it is a new review criteria upon which reviewers are expected

to make comments, there has been some confusion as to what qualifies as innovation. Obviously, if the grant writer does not include information addressing innovation in the proposal, no score can be assigned to that section, rendering the application unfunded. Innovation is at the "apex" of the scientific pyramid, supported by significance, hypotheses and aims, procedure and approach design, and evaluation.

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How did innovation get into the review criteria? In the early 1980s, small business entrepreneurs lobbied Congress for a set-aside from the larger federal funding agencies to encourage the development of new ideas and products. The word "innovation" became embedded in the Small Business Innovation Research (SBIR) awards of those federal agencies. SBIR innovative research was not the basic research conducted typically in academia at that time, it was not clinical research to test drugs, and it was not what we now call translational research. The term "small"

business" in this usage did not include the neighborhood pharmacy, the local beauty shop, or the locally owned, franchised fastfood restaurant. Instead, the SBIR funded businesses with fewer than 100 employees that were engaged in the development of new products or ideas for commercialization that were within the interests of the federal government. The parameters were to increase employment, meet federal needs, provide access for all groups, and increase commercialization of innovation stemming from federal projects. Innovation gradually crept into the review criteria as reviewers grappled with the quality and value-added of the research, the applicability of the research to the profession, and the limited funding for research. Agencies developed strategic plans with priorities with stated expected outcomes. All of these facets contributed to the expectation that research should have some type of application even if it is something that would occur in the future. Thus, investigators who are forwardthinking, can see the future, and can figure out the pathway to get to the future are those who will be funded.

The late Steve Jobs of Apple, Inc. was lauded as a great innovator. Perhaps the best known innovation was the introduction of the iPad TM. The iPad used no new technology—touch screens have been in existence since the mid-1980s, it is basically a computer, and the small size was not new.

Touch screens have been used in malls to identify the locations of certain types of businesses. A popular hamburger enterprise has used touch screens for entering orders into the system for years. Why? Using unskilled personnel meant that often mistakes were made in calculating tax, adding up totals, and making correct change. All of these mistakes cut into the profit margin and it was less expensive to incorporate the technology. Now, each component of an order has its own touch screen button that automatically records the price of the orders, adds taxes, deducts special discounts, totals the bill, and calculates the change from cash payments. Some computers were not much more than palm-sized more than ten years ago. The limiting factor was the size of the processing components. To overcome this, removable hard drives were inserted into or removed from the mini-computer as needed. Over time, processing components have become smaller and more powerful so that size is no longer an issue. So, if all the technology existed and it still is a computer, what made the iPad innovative? The collection of these technologies into a new format with portability and new applications (the new "apps" so highly regarded) made the iPad innovative.

Unlike Steve Jobs who integrated a number of components into a whole, Gregor Mendel was innovative in that he elected to study each plant trait independently of the others. Prior work had been done on multiple generations and multiple traits with no meaningful data. By combining his expertise in gardening with schooling in physics and mathematics, Mendel's research led to the laws of segregation and independent assortment. His choice of pea plants and traits may have been a lucky choice. The mathematical analyses led to the postulation of pairs of "factors" that we today know as genes or alleles. Any other species may have had genes grouped on one chromosome where segregation and independent assortment would not have been evident. Nevertheless, Mendel's separation of the whole into distinct parts was innovative at the time.

We consider Leonardo da Vinci to be innovative in that he designed the concept of a rotary blade mechanism that is heralded as the first helicopter design. His designs led us to believe that he had some conceptual knowledge of lift, torque, etc. Leonardo put all these ideas together even though he didn't have the funding or all the mechanisms in place to construct a helicopter.

Other innovations create a paradigm shift in the way a specific scientific procedure is done and may forever change the standards. For years, eye disease research has been done on standardized strains of laboratory mice. The ultimate test of the disease manifestations or treatment was to sacrifice the mouse and perform

histology studies on the eye. Each mouse was a one-time effort as the study was neither repeatable on that mouse nor could the eye be tested for irregularities prior to introduction of a disease vector or a treatment. The only recognized, valid results were the hundreds of histological slides obtained from each mouse eye. With the advent of light science technology, a modification of recognized, established light procedures can be used to scan the mouse eye before the introduction of a disease vector. What has been discovered is that many individuals of the "pure" strains of laboratory mice appear to have lesions in the eye prior to receiving treatment. The pre-screening does not damage the eye but allows the investigator to discard the mouse from the experiment or possibly record the lesions. Then a comparison of the end results with the known lesions permits exclusion of the known lesions from the study. The ultimate "gold standard" for eye research is histology; both histological and photonic results can be compared side by side until some degree of reliability can be established. Should prior screening and later analysis by photonic means become accepted, that would be a paradigm shift.

Creativity and innovation may be more difficult to assess in the arts. One man's creativity is another's "Ugh!" However, one example comes to mind. A print/composite artist was interested in making large murals that included original prints. A limiting

factor to the creative effort was the size of the prints that could be made from the available printing press. Others had tried to overcome this shortcoming with a variety of less than successful ways to hide the fact that the print was glued to the background. This artist took a different approach and decided to make the attachment of the print to the background obvious. This was done by stapling the print to the background with standard staples. The technique involved very consistent spacing of the staples into the board. It was quite attractive and for many years was one of the signature aspects of her print works. Again, everything existed prior to the new assembly of materials to tell a different story. Innovation may be born of necessity. Artists continually seek new media and ways to utilize that media. Digital photography and computer graphics have opened a whole new door for creativity and innovation.

Where does innovation lead us? Innovation is not necessarily going to lead to patents and profits. Some innovations become imbedded in scientific procedures and improve the accuracy with which data are collected without becoming an invention. The core of innovation may lie in how humans use a "discovery" to enhance well-being and suppress negative effects. The prehistoric discoveries of fire and the wheel come to mind. Wildfires spawned during lightning strikes, fueled with

accumulated biomass, and spread by high winds, are dangerous—they rout humans and animals from their habitat, direct lightning strikes can be fatal, and relocation to a better food source might be necessary. Over time, man learned to use the fire to enhance the quality of life—heat for personal warmth and cooking, light to see danger and to keep danger away. Man also learned to control the fire to his advantage—controlling fuel limits fire size, applying water to extinguish fire, smothering a fire with animal skins or woven mats, etc.

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Many naive investigators identify any new information to be gleaned from a proposed study as innovative without ever explaining the impact of the innovation. For years the NIH has asked that investigators identify the health-related issues to be affected by a research project. Reviewers bemoaned many of the inane responses to this—leads to more discovery, good for my career, creates articles for publication, will get me tenure, etc. All that the reviewer wanted was some evidence that the investigator could make a translational leap from bench chemistry to bedside treatment, prevention or diagnostics. The same issue

seems to be rising with the use of the term "innovation."

Some innovations arise from "figments" of one's imagination. That figment is such a small idea that it may not seem feasible. The idea may race through the mind, only to be stored in a compartment. However, the idea may continue to be revisited and may actually "gel" at a later date. Species "splitters", who are always trying to identify new species, become experts in discerning minute differences among individuals. The brain is a multivariate computer and identification of the variables will often confirm what the brain imagines is correct. What will be the innovations of the future? The media has touched on the issues—global warming and mediating the effects of global warming; storage of naturally occurring energy from the sun, wind, water, and lightning; inequality in the distribution of the world's resources and the effects of overpopulation on these resources; and unlocking brain access for all learners (potential)—to name a few. Innovation is not change for the sake of change. Innovation sheds new light on systems operation; provides better mechanistic behavior studies; engages students in a better learning experience; provides new ways to diagnose, prevent, or treat an illness; or develops offensive or defensive activities to protect people. Innovation can be high risk, and may

exhibit high vs. low importance, relevance, and significance.

ADDRESSING THE REVIEWER

How does one convince a reviewer that a change of procedures and approaches can and does lead to innovation? First, the reviewer must concede that the first major funding awarded to a novice investigator is not going to contribute earth-shattering innovation/paradigm shifts/inventions that change the world within that discipline. Instead, the innovative idea has moved past the figment era and into some more concrete arena. "Creating" a project is not just going to the other side of the mountain to see what's there but imagining, "What could be there? How can you identify it? How can it be used?"

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So what is the new investigator to do when resubmitting a grant application to address previous shortfalls or trying to really impress that reviewer with the first application? First, make sure that all your procedures are totally thought out and that as much information as needed is gleaned from each experiment. Develop appropriate

preliminary information or data that will tell the reviewer the expected results. Do a "pretend" data analysis on that information to see if you can obtain the results that you desire to prove your hypothesis. Prepare your application in such a manner that the reviewer can address one aim or objective at a time and follow each through the entirety of the application. Do the statistics and analysis. This, of course, takes more time in the planning process, but the results will pay off in the long run. Be sure to tell the reviewer why your proposed work is innovative.

There may be "levels" of recognized sophistication in innovation that affect the reviewer's evaluation of innovation in a project. These might include (in a pseudo-ascending order of importance or significance):

- Figment—Speculative ideas with no data support
- Procedures—Change in a process that reveals better data resolution or more data
- Approach—Assemble parts to make a new whole OR dissembling the whole into separate components
- Innovation—Paradigm shifts that diminish or erase significance of all previous innovations in the field; studies that address discipline tenets that have been postulated but poorly proven.

As with all innovation, there must be some aspect that possibly changes how or why we conduct business, science, teaching, performances, etc., in the future. That

innovation is based on a solid scientific background.

ABOUT THE AUTHOR

Nancy B. Bell is the Principal of Research Image, a consulting company that provides workshops and other services to institutions wishing to increase investigator grantsmanship skills. She has had more than 30 years of experience in research administration, including grant writing, principal investigator, workshop provider, and pre- and post-administration positions. Her experiences with faculty extend across a wide variety of funding agencies and academic research arenas. Upon "retirement" from the public sector, she founded Research Image to continue her work with faculty investigators. She is the developer of the SRA Grantsmanship certificate program and recently received the SRA Distinguished Faculty Award.